

ROSPRIDE

Prucalopride succinate

Consumer Medicine Information

This leaflet provides important information about using ROSPRIDE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ROSPRIDE.**

Where to find information in this leaflet:

1. Why am I using ROSPRIDE?
2. What should I know before I use ROSPRIDE?
3. What if I am taking other medicines?
4. How do I use ROSPRIDE?
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6. Are there any side effects?
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1. Why am I using ROSPRIDE?

ROSPRIDE contains the active ingredient Prucalopride succinate. ROSPRIDE acts on the muscle wall of the gut, helping to restore the normal functioning of the bowel.

ROSPRIDE tablets are used for the treatment of long-standing constipation in adults in whom conventional medicines used to treat constipation (laxatives) fail to provide adequate relief.

ROSPRIDE is not used to treat constipation due to other medical conditions including disorders which involve the over-production or under- production of hormones from the endocrine gland, disorders that involve an alteration in normal metabolism, disorders of the nervous system and constipation due to use of medicines including opioid medicines such as codeine, oxycodone and morphine.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

There is no evidence that this medicine is addictive.

This medicine is available only with a doctor's prescription.

2. What should I know before I use ROSPRIDE?

Warnings

Do not use ROSPRIDE if:

- you are allergic to prucalopride succinate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- ROSPRIDE contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.
- you are on kidney dialysis (a procedure used to remove waste products from the blood of a person with kidney failure)

- if you suffer from perforation or obstruction of the gut wall, or severe inflammation of the intestines
- if you had recent bowel surgery

Check with your doctor if you:

- If you are not sure whether you should take this medicine
- have any other medical conditions, especially the following:
 - severe kidney disease
 - severe liver disease
 - any other serious medical problem such as lung or heart disease, neurological or psychiatric disorders or other endocrine disorders, cancer or AIDS for which you are currently under supervision by your doctor
 - a history of changes in heart rate (fast, slow or irregular) or heart disease caused by reduced blood flow in the blood vessels of the heart muscle
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is recommended not to take ROSPRIDE if you are pregnant or if you intend to become pregnant, unless your doctor advises you to do so.

Talk to your doctor if you are breastfeeding or intend to breastfeed. When breast-feeding, prucalopride can pass into breast milk, and although there is no evidence that this is harmful, it is better not to use this medicine while breastfeeding unless your doctor advises you to do so.